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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,333	10/05/2004	Reddy Bandi Parthasaradhi	H1089/20018	6314

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EXAMINER

COPPINS, JANET L

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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06/30/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No. 10/510,333	Applicant(s) PARTHASARADHI ET AL.	
	Examiner JANET L. COPPINS	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 3-14, 16 and 17 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-17 are currently pending in the instant application.

Priority

2. The instant application is a 371 of PCT/IN03/00140, filed April 4, 2003.

Information Disclosure Statement

3. Applicants' Informational Disclosure Statement (IDS), submitted February 18, 2005, has been considered by the Examiner. Please refer to the signed copy of Applicants' PTO-1449 form, submitted herewith.

Election/Restrictions

4. Applicants' election with traverse of Group I, claims 1, 2 and 15 drawn to crystalline Valdecoxib Form I and its pharmaceutical composition, in the response filed April 28, 2008, is acknowledged.

5. The traversal is on the ground(s) that the special technical feature defines an advance over the prior art. This is not found persuasive because under PCT Rule 13.1:

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.

Applicants' instant claims do not relate to a single invention, the application is drawn to multiple product inventions. The multiple inventions are not so linked as to form a single general inventive concept because according to PCT Rule 13.2:

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Applicants' instant claims do not contain a special technical feature that defines a

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contribution over the prior art. The structure of Valdecocixib, as well as its polymorphic forms, are known in the art, please refer to WO 9806708, which discloses the same compounds and crystalline forms, i.e. the “special technical feature,” and supports the Examiner’s position that Applicants’ compounds fail to define a contribution over the prior art. Therefore, unity of inventions is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper and according to PCT Rule 3.3:

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Therefore, since the claims do not contain a special technical feature, which defines a contribution over the prior art, the Examiner may determine within a single claim that the inventions are not so linked as to form a single general inventive concept.

Therefore, the finding of Lack of Unity is still deemed proper.

6. Accordingly, claims 3-14, 16 and 17 are currently withdrawn from consideration as drawn to non-elected inventions.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 2 is rejected for incorporating a figure by reference, i.e. referring to the XRD of Figure I. Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table “is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience.” *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993), see MPEP 2173.05(s). The Examiner recommends incorporating the data from figure I into the claim, or using the following language, “The compound of claim 1, having the X-ray diffraction pattern with characteristic peaks expressed in d-values (A) at ...”

(b) Claim 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for crystalline “Form I” of valdecoxib with the specific XRPD found in Figure 1 and on page 2 of the specification, does not reasonably provide enablement for compositions containing said polymorphic form. Claim 15 is drafted in terms of a pharmaceutical composition comprising valdecoxib Form I. It is known in the art that polymorphs tend to convert from less stable to more stable forms. Dissolving the specific crystalline form in water, creating an aqueous solution, would put the compound in its free form and not in a crystalline form with the specific X-ray diffraction pattern as claimed. In aqueous phases, all physical forms are amorphous. Thus the metastable compound will resort back into its most thermodynamically stable form, which may have a different X-ray diffraction pattern

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than claimed, additionally, a solution prepared from a specific crystalline form and water would contain the free form of the compound. Applicants have provided no evidence to ensure that their crystalline compound will maintain the specific Form I as recited and will not resort back to the free form of the most thermodynamically stable form of the compound while in composition, therefore the claims cannot distinctly point out and claim the intended Form II.

Conclusion

10. In conclusion, claims 1-17 are pending in the application. Claims 3, 4, 16 and 17 are currently withdrawn from consideration. Claims 2 and 15 are rejected, and claim 1 appears allowable over the prior art of record.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JANET L. COPPINS whose telephone number is (571)272-0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Coppins
June 23, 2008

/Kamal A. Saeed, PhD./
Primary Examiner, Art Unit 1626